UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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DEBORAH SMITH and MICHAEL SMITH,

Plaintiffs,

-against-

JOHNSON & JOHNSON, INC. and ETHICON, INC.,

Defendants.

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CASE NUMBER

CV 07 4314

COMPLAINT AND DEMAND FOR JURY TRIAL

SIFTON, J.

AZRACK, J.

Plaintiffs, DEBORAH SMITH and MICHAEL SMITH, by their attorneys, the **LAW OFFICES OF SYBIL SHAINWALD, P.C.**, upon information and belief, at all times hereinafter mentioned, allege as follow

JURISDICTION

1. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiff is a citizen of States and citizens of a foreign state which are different from the States where defendants are incorporated and have their principal places of business. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00) as to each Plaintiff.

PARTY PLAINTIFFS

2. Plaintiff DEBORAH SMITH was at all times relevant herein a resident of the State of Mississippi.

3. Plaintiff MICHAEL SMITH, husband of Plaintiff DEBORAH SMITH, was at all times relevant a resident of the State of Mississippi.

PARTY DEFENDANTS

4. Upon information and belief, Defendant, Johnson and Johnson, Inc., is a corporation conducting business in the state of New York.

5. Upon information and belief, Defendant Ethicon, Inc., is a corporation conducting business in the state of New York.

FACTUAL BACKGROUND

6. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell, and/or distribute Mersilene mesh, a material used as an alternative to human tissue during particular types of reconstructive surgery, and Ethibond and/or VICRYL sutures (hereinafter "the products").

7. At all times relevant, Defendants secured permission from the FDA to publicly sell the products for application in humans. Defendants knew and were aware, or should have known, that the products had been insufficiently tested; that the products were defectively created, designed, manufactured, tested, formulated; were contaminated; lacked adequate warnings; and were negligently and recklessly advertised, marketed, promoted and sold.

8. Defendants made certain claims that were distributed and circulated to the medical profession and to the general public through advertising, literature, detailmen, brochures and other materials stating that the products were of a safe and efficacious material for use in various surgeries, including reconstructive surgeries.

9. At the time, these Defendants knew or should have known that the products and/or its components had the potential to become harmful to patients in whom the products were applied.

10. Upon information and belief, Defendants misrepresented the risks inherent in the use of the products in their applications to the FDA and to other governmental persons and/or agencies.

11. Defendants knew, or should have known, of the above-mentioned risks based upon the state of knowledge as it existed at that time and upon generally accepted engineering, medical and research standards and principles.

12. The Defendants, their agents, servants and/or employees, manufactured, produced, promoted, formulated, created or designed the products without making proper and sufficient tests to determine the dangers and contra-indications thereof, and without warning the public and the medical profession of the dangers and contra-indications and side effects inherent in the aforesaid material. The Defendants also negligently advertised and recommended the use of the products to the medical community without sufficient knowledge as to its dangerous propensities and/or contaminated features; represented that the products were safe for use for its intended purpose, when, in fact, they were unsafe; and failed to conduct sufficient testing programs to determine whether or not the products were safe for use. Defendants knew or should have known that the products were unsafe and unfit for use by reason of the dangerous effects, contra-indications, and because of the contamination of the facility at which and from which these products were designed, created, formulated, manufactured and produced. Defendants, their agents, servants and/or employees, improperly obtained the

approval of the FDA to market the products by misrepresenting the risks of the products to the FDA.

13. Defendants, by their agents, servants and/or employees were careless and negligent in the manufacturing, selling, distribution, merchandising, advertising, promotion, compounding, packaging, fabrication, analyzing, marketing, and recommendation of said products without making proper and sufficient tests to determine the dangers thereof.

14. By reason of the foregoing, Plaintiff DEBORAH SMITH has developed cancer, as well as other serious injuries; and Plaintiff DEBORAH SMITH has sustained severe, serious, permanent and personal injuries; will require extensive hospitalizations, medical care, surgeries, and lifelong attention; has been incapacitated from their normal functioning and will be unable to pursue normal means of livelihood; will be precluded from having a normal life, physically, intellectually, vocationally, emotionally, or psychologically; and Plaintiffs DEBORAH SMITH and MICHAEL SMITH have been otherwise grossly damaged.

COUNT I
NEGLIGENCE

15. Plaintiffs incorporate by reference all of the preceding paragraphs as though fully set forth at length herein.

16. The negligence and carelessness of Defendants, by and through their agents, servants, employees and/or ostensible agents consisted of the following:

a. Designing, manufacturing, supplying and distributing the products in a defective and/or contaminated condition when they knew or should have known of said defects;

b. Failing to act reasonably to identify, eliminate or reduce the risks of hazards associated with the intended and foreseeable uses of the products;

c. Failing to utilize existing technology or to apply established engineering, scientific and medical principles to eliminate or reduce the risks and hazards associated with the intended and foreseeable uses of the products;

d. Designing, manufacturing, supplying and distributing the products, which were unreasonably dangerous;

e. Designing, manufacturing, supplying and distributing the products, which were unsafe and defective;

f. Designing, manufacturing, supplying and distributing the products, which were unsafe for all of their intended and foreseeable purposes and uses;

g. Designing, manufacturing, supplying and distributing the products without proper safeguards, safety devices, safety appliances and safety equipment;

h. Designing, manufacturing, supplying and distributing the products, which were improper for the purpose(s) for which Defendants knew they would be used;

i. Designing, manufacturing, supplying and distributing the products without adequate warnings;

j. Negligently designing the products;

k. Negligently manufacturing the products;

l. Negligently supplying the products;

m. Negligently distributing the products;

n. Failing to comply with standards, specifications and regulations in the industry;

o. Failing to comply with federal and state statutes and regulations; and

p. Failing to act reasonably to identify, eliminate or reduce the risks of hazards associated with the intended and foreseeable uses of the products as a result of the contamination of the facility from which and at which the products were created, formulated, manufactured, produced and promoted.

q. Failing to adequately test the products, or test the products at all;

r. Failing to conduct post-marketing surveillance of the products.

17. As a direct and proximate result of the negligence and carelessness of defendant, Plaintiff DEBORAH SMITH sustained severe and disabling personal injuries, including, but not limited to, infection, a giant hernia, a secondary hernia, a fistula, sexual dysfunction, scarring, injuries to her bones, muscles, ligaments, tendons, blood vessels, nerves and nervous system; and emotional, psychological and psychiatric injuries, all of which are permanent in nature.

18. As a direct and proximate result of the negligence and carelessness of the defendants, Plaintiff DEBORAH SMITH has in the past and will in the future suffer excruciating and agonizing aches, pains, mental anguish, pain and suffering and humiliation.

19. As a direct and proximate result of the negligence and carelessness of the defendants, plaintiffs have in the past and will in the future be forced to expend vast sums of money for medical care that would otherwise be unnecessary, but for the negligence of the defendants.

20. As a further direct and proximate result of the negligence and carelessness of the defendants, Plaintiff DEBORAH SMITH has been and will be disabled from performing

her usual duties, activities and occupations with a consequent loss of earnings and earning power.

21. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

COUNT II
STRICT LIABILITY

22. Plaintiffs incorporate by reference all of the preceding paragraphs as though fully set forth at length herein.

23. Defendants, by and through their agents, servants, employees and/or ostensible agents is strictly liable to Plaintiffs because at all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, sold, purchased, prescribed, and had administered the products as hereinabove described in violation of the applicable statutes, regulations and appropriate standards of care.

24. The products was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

25. At those times, the products was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, the general public and, in particular, the Plaintiffs herein.

26. Defendants, while regularly engaged in the business activities aforementioned, did design, develop, manufacture, produce, test, sell, market and/or

distribute the products, which were surgically applied to Plaintiff DEBORAH SMITH.

27. At all times herein mentioned, the products were in a defective condition and unsafe and Defendants, individually, jointly and severally, knew or had reason to know that the products was defective and unsafe in violation of the application statutes, regulations and appropriate standards of care.

28. The products were inherently dangerous.

29. At the time of the occurrence, the products were being used for the purposes and in a manner normally intended.

30. By the exercise of reasonable care, neither Plaintiff could have discovered the defects herein mentioned and/or perceived their danger.

31. As a direct and proximate result of the defective condition of the products manufactured and supplied by Defendants, Plaintiffs were caused to sustain severe and grievous personal injuries, as described herein.

32. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiffs for the marketing of defective products.

33. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

34. Plaintiffs incorporate by reference all of the preceding paragraphs as though fully set forth at length herein.

35. In manufacturing, marketing, distributing and selling the products, Defendants owed a duty to users, including Plaintiff DEBORAH SMITH, to provide products, which were fit for the ordinary purpose for which they were used, and to ensure that the products conformed to the promises and affirmations made to the ultimate consumer, in this case, Plaintiff DEBORAH SMITH.

36. Defendants knew or should have known that the general public and Plaintiffs in particular, relied on them to provide both products which were fit for their ordinary or intended use and which would conform to the promises and affirmations concerning them.

37. Defendants impliedly warranted to Plaintiffs that the products were safe and suitable for use, particularly in a surgical setting.

38. Defendants, as more specifically set forth above, breached their duties and the implied warranties of merchantability.

39. As a direct and proximate result of the Defendants' breaches of their duties and implied warranties of merchantability, Plaintiffs were caused to sustain severe and grievous personal injuries, as described herein.

40. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

COUNT IV
BREACH OF EXPRESS WARRANTY

41. Plaintiffs incorporate by reference all of the preceding paragraphs as though fully set forth at length herein.

42. Defendants expressly warranted that the products were safe and suitable for use as a substitute for human tissue in certain types of reconstructive surgery.

43. The products failed to conform to the express warranties of the Defendants.

44. As a direct and proximate result of the Defendants' breaches of their duties and express warranties, Plaintiffs were caused to sustain severe and grievous personal injuries, as described herein.

45. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

COUNT V
LOSS OF CONSORTIUM

46. Plaintiffs incorporate by reference all of the preceding paragraphs as though fully set forth at length herein.

47. The personal injuries that Plaintiff DEBORAH SMITH has suffered as a direct and proximate result of the negligence, recklessness and the other conduct giving rise to liability in this case, as described herein, have resulted in loss of companionship, affections, society and other aspects of Plaintiff MICHAEL SMITH's marital relationship with Plaintiff DEBORAH SMITH.

48. Plaintiff MICHAEL SMITH's loss of consortium is a direct and proximate result of the negligence, recklessness and the other conduct of Defendants giving rise to liability in this case, as described herein.

49. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs DEBORAH SMITH and MICHAEL SMITH demand judgment against each Defendant on each cause of action with interest together with the costs and disbursements of this action.

Dated: 10/9/07

New York, New York

By: _____

Sybil Shainwald (SS-1554)
111 Broadway, Suite 403
New York, New York 10006
(212) 425-5566

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

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SYBIL SHAINWALD (SS-1554)